REMARKS

The Examiner rejected claims 33-36, 38 and 41 under 35 USC 103(a) as being unpatentable over Davis-Lemessy et al. (6,139,525), and claims 39 and 40 under 35 USC 103(a) as being unpatentable over Davis-Lemessy et al. in view of Okuda et al. (6,053,939). Claims 33-36 and 38-41 are pending.

The Examiner states, in part, that Davis-Lemessy et al. discloses a balloon catheter having a fusion bond containing a compatibilizing material, and that the compatibilizing agent may be used alone or in combination with a surface treatment of one or both opposed surfaces, the surface treatment consisting of a plasma treatment applied to either the surface of the balloon, the surface of the shaft, or both, and the surface treatment acts by providing functional groups and increasing surface area which facilitates fusion bond formation between the compatibilizing agent and the shaft and balloon, and that that preferred compatibilizing agent is ethylene acrylic ester and an ethylene acrylic acid copolymer, and that although Davis-Lemessy et al. does not teach that the acrylic layer of the compatibilizing agent is 10-150 nm in thickness, it would have been obvious to optimize the thickness of the compatibilizing layer as taught by Davis-Lemessy et al. given that the thickness of a coating can be controlled to obtain specific properties and it is desirable to obtain a thin coating thickness for a bonding layer.

However, Davis-Lemessy et al. does not disclose or suggest a plasma polymerized film layer along an entire length of a balloon first layer, with the balloon second layer bonded to the plasma polymerized film so that the plasma polymerized film is between the first and second layers, and the plasma polymerized film has a thickness which is

about 10 to about 150 nanometers and which is not fused with the material of the first layer, as required by the embodiment of Applicant's amended claim 33.

Support for the amendment to claim 33 can be found at paragraph [0012] disclosing that the deposited plasma polymerized thin bulk film has the same composition as the surface, and paragraph [0021] disclosing that the entire length of at least an inner surface of an ePTFE layer of the balloon has a plasma polymerized film.

Davis-Lemessy et al. discloses a hot melt adhesive compatibilizing agent which is compatible with both the balloon and the shaft, wherein the compatibilizing agent melts along with the balloon and shaft surfaces during fusion bonding so that the resulting fusion bond contains balloon, shaft, and compatibilizing material intimately intermixed with no remaining compatibilizing agent independent of the shaft and balloon material (see col. 3, lines 1-10). Thus, although Davis-Lemessy discloses that the compatibilizing agent can be applied as a solution coated onto the surface of the balloon or as a short cylindrical collar configured to be received against the balloon inner surface, in Davis-Lemessy the compatibilizing agent is bonded to the balloon surface by forming a fusion bond which fuses all three of the materials (balloon, shaft, and compatibilizer). In contrast, by plasma polymerizing a film onto the first layer of the balloon, the resulting film does not form a mixed, fused molten polymer bond. Rather, it deposits and bonds to the first layer such that the film has the same bulk and surface composition. That is, because the film bonds to the first layer as it is plasma polymerized onto the first layer, the resulting thin plasma polymerized film, which has the same composition in the bulk and at the surface, is thus not mixed by fusing with the material of the first layer, unlike

Davis-Lemessy. Although the second layer of Applicant's balloon may fusion bond to the plasma polymerized film, fusion bonding which melts the first and second layer materials and the film to result in a fusion bond containing all three mixed materials is not formed in the embodiment set forth in Applicant's amended claim 33.

Moreover, in Davis-Lemessy et al., the catheter 10 has the compatibilizing agent along the ends of the balloon 12 for bonding to the shaft 11 and not along inflatable length of the balloon between the bonded ends, and thus not along the entire length of the balloon.

In the Response to Arguments section of the Office Action, the Examiner states while Applicants submitted that it would not have been obvious to optimize the thickness of the compatibilizing layer as taught by Davis-Lemessy, the Examiner disagrees and maintains that the thickness of the compatibilizing layer as taught by Davis-Lemessy et al. can be optimized to obtain specific properties and a thin coating is desirable for a bonding layer.

However, irrespective of whether the compatibilizing agent can be optimized, Davis-Lemessy et al. teaches away from a coating as thin a Applicant's plasma polymerized layer. Specifically, Davis-Lemessy et al. discloses that irrespective of the method used to apply the compatibilizer layer, the compatibilizing agent thickness should range from about 0.5 mm to about 4.0 mm (see col. 5, lines 41-45). The compatibilizing agent, preferably a hot melt adhesive, fusion bonds to both the material of the balloon and the material of the shaft. The hot melt adhesive compatibilizing agent is therefore applied as a relatively thick layer between the balloon and shaft, unlike the relatively thin

film required by Applicant's claims. Therefore, Davis-Lemessy teaches away from a compatibilizing layer with a thickness at least 3 orders of magnitude smaller than the thickness which Davis-Lemessy states should be used (i.e., Applicant's 150 nm thickness film vs. Davis-Lemessy's 500,000 nm (0.5 mm) thickness compatibilizer).

The compatibilizing agents of Davis-Lemessy referred to by the Examiner (ethylene acrylic ester maleic anhydride and an ethylene acrylic acid copolymer) are polyethylene based adhesives. As discussed in Applicant's specification at paragraph [0004], relying solely on adhesives is not ideal for flexibility or bond strength.

The Examiner further states that Davis-Lemessy et al. discloses that the compatibilizing agent may be used alone or in combination with a surface treatment of one or both opposed surfaces, the surface treatment consisting of a plasma treatment applied to either the surface of the balloon, the surface of the shaft, or both, and the surface treatment acts by providing functional groups and increasing surface area which facilitates fusion bond formation between the compatibilizing agent and the shaft and balloon. However, the specific surface treatments disclosed by Davis-Lemessy et al. are an alcohol primer or an Argon plasma cleaning treatment, where any modification/functionalization which results therefrom does not result in a thin plasma polymerized acrylate or fragmented acrylate polymer film covalently bonded to the surface of the catheter component. In fact, Applicants similarly disclose that "[t]he section may be first treated with an argon plasma to prepare the surface prior to exposure to the plasma polymerized film deposition", "to remove organic processing debris from the surface of the ePTFE film before deposition of the plasma polymerized film" (see

paragraphs [0011] and [0023]). Thus, although Davis-Lemessy refers generally to "a plasma treatment", the terminology "plasma treatment" refers to an Argon plasma stream conventionally used for preparing a surface for bonding. Although the compatibilizer of Davis-Lemessy is an acrylic acid copolymer, there is no teaching or suggestion that the "plasma treatment" of Davis-Lemessy provides a deposited plasma polymerized acrylate or fragmented acrylate polymer film as required by the embodiment of Applicant's claim 33.

The Examiner rejected claims 33-36, 38, 39 and 41 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 8 of U.S. Patent No. 6,946,173, stating, in part, that claims 1, 7 and 8 of the '173 patent recite a balloon catheter having a balloon having a first layer of expanded PTFE and the first layer has a plasma polymerized functionality bonded to at least a section thereof. However, contrary to the Examiner's assertion claims 1 and 7 of the '173 patent to do not recite a plasma polymerized functionality bonded to at least a section of the balloon first layer. Only claim 8 recites a plasma polymerized functionality, but claim 8 depends from claim 1, and claim 1 further requires an elastomeric polymeric material which impregnates the porous polymeric material of the first layer and which is compatible with, and different than, the elastomeric polymeric material of the second layer and that the second layer has a radial tensile set of about 0% to about 10% based on a radial expansion of at least about 300% of an initial diameter, which could not have been claimed in the instant (earlier filed) application. Therefore, Applicants respectfully request that the double patenting rejection be withdrawn.

In light of the above amendments and remarks, applicant respectfully requests reconsideration and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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